KNOWLEDGE, ATTITUDES, AND BEHAVIORS OF PATIENTS REGARDING INTERDENTAL DEPLAQUING DEVICES: A MIXED METHODS STUDY

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ABSTRACT

Avie Jackson Thompson Smith: Knowledge, Attitudes, and Behaviors of Patients Regarding Interdental Deplaquing Devices: A Mixed Methods Study
(Under the direction of Rebecca S. Wilder)

This mixed-methods study assessed patients' oral health literacy, motivation, and barriers regarding interdental deplaquing. Participants (n=49) from a study comparing Glide® Pro-Health Floss Original (F) and GUM® Curved Soft-Picks® Advance (SP) completed daily diaries and questionnaires discussing motivation, tiredness, confidence and satisfaction for their deplaquing method. Results were analyzed by Mantel-haenszel chi-square tests. Nineteen of 49 participants attended focus groups (F and SP) about oral health behaviors, literacy, motivators and barriers regarding interdental deplaquing. Discussions were digitally recorded, transcribed, and analyzed in ATLAS.ti 7.5.15. F users reported statistically significant higher agreement about ability to remove food/debris (p=.01), cleaning thoroughly (p=.02), and clean feeling of the mouth (p=.01). SP users reported higher ease/efficiency of use (p=.01), convenience (p=.003), easy to hold (p=.0001), and easy use away from home (p=.008). Daily diaries revealed higher motivation/ ease of use (SP). Barriers to interdental deplaquing (e.g. low literacy) may hinder patients' motivation to comply.

To my relentless and loving God.

No matter how I might stray, you have always been my protector and guiding light.

“God is within her, she will not fall.” Psalm 46:5

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LIST OF ABBREVIATIONS

DH	Dental Hygienist
F	Glide® Pro-Health Floss Original
NHANES	National Health and Nutrition Examination Survey
OHL	Oral Health Literacy
SOD	UNC Chapel Hill School of Dentistry
SP	GUM® Curved Soft-Picks® Advance

INTRODUCTION

According to the National Health and Nutrition Examination Survey (NHANES) from 2009-2012, 46% of US adults ages thirty and older had periodontitis.[1] Medical and dental professions have come to the consensus that good oral health important to overall health, given that periodontal disease has been linked to systemic conditions like cardiovascular diseases and diabetes.[2–8]

The American Academy of Periodontology defines chronic periodontitis as "the inflammation of periodontal tissues resulting in clinical attachment loss, alveolar bone loss and periodontal pocketing."[9] Periodontal diseases are caused by improper removal of biofilm, also known as plaque biofilm. Infectious diseases, such as periodontal diseases and dental caries, are caused by a shift in the biofilm of gram-positive to gram-negative bacteria.[10,11] Periodontal diseases are not caused solely by bacteria. Risk factors for periodontal diseases that can be controlled are smoking, diabetes mellitus, and psychological factors.[2,12–14] Risk factors for periodontal diseases that cannot be controlled are genetics, host response to bacteria in the oral cavity, osteoporosis, some systemic diseases and aging.[12,15–18] Periodontal diseases are mostly preventable through proper oral hygiene care, including toothbrushing and interdental deplaquing. Despite this knowledge, patient compliance with interdental deplaquing remains a concern.

Interdental Cleaning Compliance

According to the Delta Dental survey in 2014, only four out of ten Americans floss daily and 20% of Americans never floss.[19] A NHANES study reported that 32% of the individuals never floss and revealed groups who were more likely to report never flossing, including: males over females, age group 75 and older than 30-44 years of age, non-Hispanic blacks and Hispanics over non-Hispanic whites, and low-income patients over higher income brackets.[1,20]

There is no current data on the prevalence of use with other interdental aids. Despite the evidence shown that periodontal diseases can affect the patients systemically and interdental deplaquing can help prevent the disease; lack of compliance with interdental deplaquing is an ongoing issue with patients leading to the high prevalence of periodontal diseases. In order to devise a plan to increase compliance, it is first required to identify what barriers or limitations are causing the behavior.

Oral Health Literacy (OHL)

Lower OHL is related to poorer oral health such as periodontal diseases and caries.[21–24] A patient with higher OHL can communicate more efficiently with their oral care provider leading to frequent dental care because of fewer complications accessing care, understanding the importance of preventive actions, and sharing critical information with their providers.[25] These patients also tend to report better oral health because they tend to follow dental recommendations, since they can understand what they are being taught.[25] To increase compliance one must first enhance patient understanding.[26] Therefore, practitioners and health professionals must embrace conceptual knowledge to improve patients decisions about oral

health.[26] Increase in OHL may increase compliance when guidance is provided with a successful behavioral change model.

Motivational Theory

Flossing compliance has shown improvement after motivational messages discussing the benefits of flossing and dangers of not flossing.[27] Increasing perceived control and intrinsic motivation, with persuasive messages, show a significant positive effect on flossing behavior.[28] Behavioral change approaches like the Transtheoretical Model [29] can help with motivational interviewing, a patient-centered technique used to inspire changes in behavioral health.[30]

Purpose

The purpose of this study was to use the patient perspective to investigate patient compliance and motivation with at-home interdental deplaquing devices. It was used to identify patient barriers, motivation level and OHL regarding interdental deplaquing. This information will add to existing literature about ways to increase patient compliance with at-home oral care. Specific aims of this study were to determine: what prevents a patient from complying to interdental deplaquing and what would motivate them to comply at-home?

REVIEW OF THE LITERATURE

According to the NHANES study from 2009-2012, 46% of US adults ages thirty and older had periodontitis. Sixty-three and a half percent of patients with periodontal disease were Hispanic, 59.1% were non-Hispanic blacks, and 40.8% were non-Hispanic whites. The prevalence was highest in patients with less than a high school diploma, current smokers, and 100% below the poverty line. Severe periodontitis was found in 8.9% and most commonly in males 50 and older.[1]

Periodontal disease has been linked to systemic conditions.[2–8] It is mostly preventable through proper oral hygiene care, including toothbrushing and interdental plaque control. Despite this knowledge, patient compliance with interdental plaque control remains a concern.

Definition/Etiology of Periodontal Disease

Gingivitis is defined as inflammation of the gingiva indicated by redness, swelling, and bleeding and is most commonly caused by the toxins of biofilm.[31] If left untreated, gingivitis may progress into periodontitis.[31] Gingivitis and periodontitis are caused by improper removal of biofilm, also known as plaque biofilm, in a susceptible host. If biofilm is left undisturbed for longer than seven days the environment can shift to the gram-negative bacteria.[10,11]

It is well known that periodontitis is caused by bacteria and a poor host response. However, risk factors for periodontal disease that can be controlled are smoking, diabetes mellitus, and psychological factors.[2,12–14] Other risks for periodontitis that cannot be controlled

are genetics, host response to the bacteria in the mouth, osteoporosis, some systemic diseases and aging.[12,15–18]

Periodontitis Link to Systemic Conditions

Periodontitis prevention is critically important due to the local and systemic effects of the disease. The medical and dental professions have come to the consensus that good oral health is important for overall health.[7]

C-reactive protein is a protein that increases in the plasma as an indication of inflammation and may act as an immune response.[32,33] Bansal et al. conducted a systematic review that reported c- reactive protein levels in the blood are elevated in patients with chronic periodontitis.[34] The body's response to the inflammation of periodontitis,[35] is why investigations have continued to study a link to diabetes, cardiovascular disease, and several other conditions.[3,35]

Cardiovascular Diseases and Periodontitis

Chronic periodontitis has been associated with an increased incidence of cardiovascular events. Frohlich et al. conducted a study to find if there was a correlation between periodontitis and chronic heart failure.[36] Results indicated that the occurrence and severity of periodontal diseases are higher in patients with chronic heart failure, when compared with the general population; however, the severity of periodontitis did not directly correlate with the cause of chronic heart failure or the extent of its symptoms.[36] Bengtsson et al. reviewed panoramic radiographs of 499 subjects, and 39.1% of the subjects showed carotid arterial calcifications. Of these subjects, 18.4% were diagnosed with periodontitis. The analysis showed that patients with periodontitis had a higher occurrence of carotid calcifications, suggesting an association between

the two.[37] Periodontal treatment has shown endothelial function improvement and decreasing biomarkers for atherosclerotic disease, especially in patients with current cardiovascular disease.[38] Matthews et al. further investigated this information and found that periodontal disease has the same physiological effects such as inflammation, coagulation effects, and insulin resistance that was indicated in the tested biomarkers. Although no causal effect has been identified, these findings show why chronic periodontitis may have an association with coronary heart disease.[3]

Diabetes and Periodontitis

The inflammatory effects of periodontitis cause an increase in cytokines resulting in systemic inflammation. Diabetes and periodontitis demonstrate a bidirectional relationship, meaning, diabetes can increase the risk of periodontitis just as periodontitis may influence the control of diabetes.[2] Oral infections have been linked to poor glycemic metabolism and atherosclerosis.[2] This evidence indicates that chronic periodontitis control may help with glycemic control for Type 2 diabetes and glycemic control may help control chronic periodontitis.[2,14] The systemic inflammatory response caused by periodontal infections may also lead to an increase in insulin resistance.[14] Periodontal therapy provided to patients with diabetes has shown improved glycemic control.[14] Matthews et al. conducted a pilot study that followed diabetic and non-diabetic patients for three years. This study discovered that patients with adequate diabetic control had good oral health, but those with poor diabetic control had greater risk of reoccurring periodontal disease.[4,39] A systematic review of 10 studies showed a statistically significant increase in risk for gestational diabetes in women with periodontal disease versus pregnant women without.[40]

These discoveries of the implications on systemic health add a significant importance to mechanical plaque removal, even if one does not include the concern for caries and periodontal diseases. Mechanical plaque removal should be advocated for regular intervals and education provided regarding its positive effects.

Mechanical Plaque Removal

Successful mechanical plaque removal can be completed through multiple avenues. It is a dental hygienists' (DH) responsibility to assess their patients and recommend dental aids according to each patients' needs and abilities. This requires the DH to complete a comprehensive exam including medical history, intra and extra oral exam and discuss with the patient their goals and limitations in their homecare. Since interdental aids come in a variety of choices (floss, interdental brushes, single tuft brushes, interdental tips, toothpicks in holder, wooden interdental cleaners, and oral irrigators) it is necessary for the DH to consider dexterity, periodontal status, embrasure space and patients' oral condition to indicate proper interdental device.[41,42]

At-home mechanical plaque removal is conducted via toothbrushing and interdental plaque control devices. De Freitas et al. investigated the effect of self-performed plaque control on gingival inflammation.[43] During this trial, subjects with no clinical attachment loss were instructed to floss and brush at different intervals of time (12, 24 and 28-hour increments); gingival and plaque indices were taken at baseline and the end of 30 days.[43] The authors found that self- performed mechanical plaque control must be conducted on a 12-24 hour basis to maintain gingival health.[43]

Toothbrushing (manual and powered) is the most widely used aid for biofilm control. Toothbrushes have been the primary source for plaque removal, as they provide mechanical disruption of biofilm and are necessary to control oral disease.[44] Studies have reported a 24-61% reduction in plaque from toothbrushing.[45] In order to thoroughly remove biofilm, both a toothbrush and an interdental mechanical aid are necessary.[46]

Bergenholtz et al. showed that using dental floss removes a significantly higher amount of plaque than a toothpick.[47] There was a slight indication that waxed floss may be more efficient than unwaxed floss in a patient; however, investigators concluded that the motivation and education of the patient is more effective than the aid they use.[47] In one study, young adult patients who had interproximal bleeding, but not periodontitis, showed a decrease in inflammation by 71% after 3 months of flossing.[48] In 1998, Christou et al. compared the effectiveness of flossing to interdental brushes.[49] After taking a baseline measurement and completing a reevaluation 6 weeks later; there was a significant decrease in the patients plaque scores, probing depths and bleeding indices for both devices.[49]

Interdental Plaque Control

Toothbrushing alone is not effective in removing plaque from the interproximal surfaces; therefore, interdental devices are needed for complete oral hygiene care. A study of Australian adults showed that regular interdental plaque control was associated with a lower level of plaque, calculus, and gingivitis.[50] Sambunjak et al. conducted a systematic review of 12 randomized controlled trials in adults to determine the effectiveness of flossing in addition to toothbrushing. The results supported that flossing in addition to toothbrushing, showed a statistically significant reduction in gingivitis than toothbrushing alone.[51] While dental floss is the most traditional

approach, studies have shown that using other interdental devices, in conjunction with a toothbrush, have been just as effective in reducing bleeding and plaque scores.[41,52–54]

Effectiveness of Interdental Devices

Salzer et al. completed a meta-review to investigate the effect of mechanical interdental plaque removal in addition to toothbrushing.[55] Six systematic reviews agreed that all interdental devices do help with removal of plaque and control of gingivitis, but to different extents.[55] Slot et al. reported on a systematic review of interdental brushes and their effect on periodontal inflammation. They found that in 9 studies toothbrushing along with interdental brushes removed more plaque, and showed a positive significant difference in plaque and bleeding scores, as well as, probing depths than toothbrushing alone.[56] A review by Rasines et al. also concurred with Slot et al. that use of interdental brushes with toothbrushing removed the most plaque.[57] Vassiliki et al. conducted a 6 week study to compare the efficacy of floss versus interdental brushes in reduction of plaque, gingival inflammation and probing depths.[49] A baseline measurement was taken and participants were provided with oral hygiene instructions at the baseline appointment and at week 3.[49] Participants used traditional floss on one side of the mouth and interdental brushes on the other side, as an adjunct to their toothbrushing.[49] Results showed that interdental brushes removed more interproximal plaque than floss and their probing depths were shallower.[49]

Water jet devices provide a pulsating and pressure action allowing for compression and decompression of the tissues to help flush medicaments subgingivally.[58–60] Numerous studies have been conducted on oral irrigation. Barnes et al. conducted a 28 day clinical trial with 105 subjects comparing three oral health routines; manual brush and water jet, manual brush and floss, and sonic brush with water jet. When combined with a sonic or manual brush the water jet

was just as effective as a manual brush and floss in removing plaque and significantly better in reducing bleeding.[52] Sharma et al. supported this by finding that adding a water jet with an orthodontic tip was more effective than floss with a threader or just brushing alone in order to remove plaque and reduce bleeding.[61]

In a four week single-blind study of 82 subjects, participants were assigned to use a water flosser or an air flosser in order to assess the reduction of gingivitis.[62] Upon beginning of the study, baseline tests were performed to assess gingivitis, bleeding on probing, and plaque.[62] The water flosser proved to be significantly more effective than an air flosser in reducing gingivitis and plaque.[62] Gorur et al. studied the effect of plaque biofilm removal by a water jet.[63] Four extracted teeth were thinly sliced into 10 pieces, some were used as a control, others were either inoculated and placed in saliva and incubated or treated with a orthodontic jet tip and not put into saliva.[63] The standard jet tip removed 99.9% biofilm in saliva and the orthodontic jet tip removed 99.84% with three seconds of use.[63] The conclusion was that due to low compliance in flossing, clinicians should be able to offer another alternative that is just as effective.[58]

SP are a tapered design, with flexible rubber bristles, that can be used in healthy mouths as well as around fixed bridges, implants and orthodontic appliances.[41] They have shown to be as effective as floss in removing interproximal plaque.[41,64] GUM® Go-Betweens® proxabrush cleaners have three sizes designed to fit into small, moderate or wide embrasure spaces and are colored accordingly.[41] GUM® Eez-thru flossers can be used for patients who have dexterity problems and some have extra benefits added, like fluoride and xylitol.[41] Rubber tip stimulators have long handles for patients with dexterity issues to clean wide interproximal embrasure spaces.[41]

Compliance with Interdental Plaque Control Devices

Buunk-Werkhoven et al. conducted a study of 487 participants regarding determinants of oral hygiene behaviors.[65] Over two-thirds of the participants reported brushing two times a day for two minutes, as recommended, only one-fourth of participants reported using interdental aids once a day, as recommended.[65] There is no current data on the prevalence of use with other interdental aids. Despite the evidence shown that periodontitis can affect patients systemically and interdental plaque control can help prevent periodontitis; there is still a lack of compliance at home. More studies are needed to determine why there is such a lack of compliance and its possible causes.

Determinants of Home Oral Health Care

Lack of compliance with interdental plaque control is an ongoing issue with patients, resulting in a high prevalence of periodontal diseases. In order to devise a plan to increase compliance, it is required to first identify what barriers or limitations are causing the behavior. Restrictions can be physical as well as psychological.

Aguirre-Zero et al. reported that the Mexican-American population is large and rapidly expanding with documented disparities in oral health care use; therefore, understanding the cause of these disparities is of public health significance.[66] Their research included adolescent and adult Mexican-Americans regarding their oral health behaviors such as toothbrushing, flossing and seeking preventive care to identify barriers and beliefs that might affect their oral health. Eighty-one percent of the adults in the study thought that flossing was important, but only 63% reported they were likely to floss once a day.[66] When asked about the lack of compliance, 69% of adults stated that it caused their gums to hurt and bleed and that they were not sure about

correct technique. Fifty-six percent of adults reported only flossing when there was food trapped between their teeth.[66] Another barrier mentioned by 69% of the adults was the lack of media messages regarding changes in lifestyle to affect oral health.[66]

Buunk-Werkhoven et al. examined potential predictors of oral hygiene care including toothbrushing, interdental plaque control, and tongue brushing.[65] Four hundred eighty seven participants answered a questionnaire regarding oral hygiene behavior, attitudes, social norms, perceived behavior control, oral health knowledge and expected social outcomes.[65] Participants reported much value to positive social outcomes that were associated with healthy teeth and had good oral health knowledge. The first part of the study used the questionnaire to help develop a new index for assessing oral hygiene behaviors in individuals. Perceived behavior control, defined as a person's perception of their capability to perform a behavior, was the best predictor of oral hygiene behavior.[65] Kamalikhah et al. recruited 653 high school students to fill out two self-administrated questionnaires that included demographics, perceived benefits and barriers, self-efficacy, a process of change in flossing behavior and its psychological determinants.[67] Flossing behavior was related to self-efficacy, perceived benefits, low perceived barriers and process of changes.[67]

Periodontal Literacy

OHL can be defined as the knowledge about good oral health behaviors and consequences of poor oral health, access to this knowledge and how to access professional dental care.[21] OHL is the ability to understand how to take medications and provider recommendations.[22] Health literacy does not reflect intelligence or education of a patient, but can be associated with patient prognosis, compliance and mortality. Unfortunately, it has been documented that most dental staff are not aware of this patient issue.[68] OHL is related to oral

health statuses like periodontal disease and dental caries. Lower OHL is related to poorer oral health.[21]

Most people are familiar with the basics of dentistry and prevention techniques, but one study showed that the elderly were not familiar with the concept of periodontal disease, children's health or oral cancer.[69] Wehmeyer et al. conducted a study to investigate OHL in periodontal patients and its association with periodontal health status.[22] Participants were new and referred patients in the University of North Carolina Periodontology clinic.[22] The study used the Rapid Estimate of Adult Literacy-30 (a dental word recognition instrument) to measure OHL, and a clinical periodontal examination was completed on 128 participants.[22] The results indicated a significant association between OHL and periodontal health in patients. Reporting that the lower the OHL related to the severity of periodontal disease.[22] In another study, results showed that in Irbid city, 71 percent of pregnant women knew the main cause of periodontal disease, 56 percent did not think they needed to increase their toothbrushing habits during pregnancy, and only 5.1 percent believed that there might be a link between periodontal disease and preterm labor.[70] There was also poor awareness about their oral health state in pregnant women.[70] Health professionals discuss many aspects with pregnant women but do not discuss increased risk of periodontal disease, therefore, limiting their knowledge.[70] Women with a lower educational level had less knowledge of periodontal disease and its cause by plaque.[70] There was no relation between age, number of pregnancies, or educational level regarding knowledge of periodontal disease.[70]

Health literacy can be separated into word recognition, reading comprehension, conceptual knowledge and communication skills.[26] Most oral health materials require an eighth-grade reading level, but approximately 40 million people cannot read materials of this level at all

and 90 million are not able to completely comprehend it.[25,71] This is why it is important to reevaluate these materials and even more important for dental staff to communicate with a patient in a way they will understand.[25] Dental hygienists can enhance their patients' role in their home care by performing brief health literacy screenings to adjust their oral hygiene instructions individually using nontechnical language, and encouraging patient questions.[68]

There are many reasons why a patient may not attend a dental appointment, but patients who have limited oral health information sources are more likely to skip their dental appointments.[72] Studies show that parents with low OHL, unemployment status, and rural living were associated with a high caries rate and poor health outcomes in their children's oral health.[23,24,73,74]

A patient with a higher health literacy can communicate more efficiently with their oral health care provider. This may lead to regular dental care due to fewer complications accessing care, understanding the importance of preventive actions, and voicing the critical information for their providers. These patients also tend to report better oral health because they tend to follow dental recommendations since they can understand what they are being taught.[25]

Practitioners and health professionals must embrace conceptual knowledge to improve patients decisions about oral health.[26] In 2003, a national assessment of adult literacy was conducted to determine adults' abilities to read and understand health information.[75] This information should be used to identify the level of health literacy, deliver information to target these specific levels, and design programs to increase health literacy.[76] To increase compliance, one must first enhance patient understanding.[26] Holtzman et al. recommended that dentists measure their patients' understanding of dental terms and periodontal disease knowledge before

providing patient education.[77] Dental professionals should be educating their patients, and there needs to be community-based educational messages to reach those not in a dental chair.[69]

Motivational Theory

The Transtheoretical Model was developed by Prochaska et al.[78] consisting of stages of change, processes of change, decisional balance, and self-efficacy as an approach to modify behavior.[29] It has been applied to smoking cessation and cancer programs, and has been suggested for application to dental hygiene.[29] In 2003, a model was developed and tested to aid patients step by step in the behavioral change of oral self-care;[79] however, at this time there is not a published study using this model.

An oral health promotion program about self-management gave an incentive of free dental treatment in hopes that this would cause behavior change for regular dental flossing in an Indian periodontal population.[80] It was found that the promotional program had a positive effect on the intention of flossing for patients with the diagnosis of periodontitis.[80] One study showed a significant change in self-reported flossing one week after an experimental manipulation by giving two articles to two separate groups, one emphasizing the benefits of flossing and the other article highlighting the dangers of not flossing.[27] Both groups reported better flossing habits after the motivational message was provided.[27]

One study of undergraduate and graduate students attempted to change flossing behavior by manipulating perceived control and motivation through persuasive messaging.[28] They found that increasing perceived control with intrinsic motivation, through brief intervention, via persuasive messaging showed a significant effect on flossing behavior after one week.[28]

Motivational interviewing is patient-centered and used to inspire changes in behavioral health. Kopp's systematic review showed that the use of this particular interviewing in adjunct to periodontal therapy could positively influence clinical and psychological factors in the context of oral hygiene.[30]

Purpose

The purpose of this study was to investigate patient compliance with two interdental plaque control devices and assess motivators for the use of an at-home interdental plaque control device. Specific aims of this study were to determine: what prevents a patient from complying with use of interdental plaque control devices and what would motivate a patient to be compliant with an at home interdental plaque control device?

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INTRODUCTION AND REVIEW OF THE LITERATURE

Mechanical plaque removal is the use of toothbrushing and interdental plaque control devices. Interdental aids come in a variety of choices (floss, interdental brushes, single tuft brushes, interdental tips, toothpicks in holder, wooden interdental cleaners, and oral irrigators). The dental hygienist (DH) should consider dexterity, periodontal status, embrasure space and evidence for use of the aid when making appropriate patient recommendations.[1–3] In order to thoroughly remove biofilm, toothbrushing and interdental deplaquing with a mechanical aid are necessary.[4] According to De Freitas et al., interdental deplaquing should be conducted on a 12-24 hour basis to maintain gingival health.[5] Regular interdental plaque control has shown a decrease in inflammation, bleeding, plaque scores, calculus and probing depths.[6–8]

There are conflicting reports in the literature regarding flossing effectiveness. Three systematic reviews, with 12 randomized controlled trials in adults and 18 studies, were completed[9] to determine the effectiveness of flossing in addition to toothbrushing.[9–12] The results supported that interdental plaque control, in addition to toothbrushing, showed a statistically significant reduction in gingivitis than toothbrushing alone.[10] Salzer et. al published a systematic review to compare the efficacy of other interdental plaque control devices to floss and found a consensus in six studies that all interdental devices do help with removal of plaque and control of gingivitis, but to different extents.[13] Toothbrushing along with interdental brushes removed more plaque[7,9,11] and showed a positive significant difference in bleeding scores, as well as pocket depth, than toothbrushing alone.[11] Soft-picks® (SP) are a tapered design with flexible rubber

bristles that can be used in healthy mouths, as well as around fixed bridges, implants and orthodontic appliances, and have been shown to be as effective as floss in removing interproximal plaque.[1,14]

According to the Delta Dental survey in 2014, only four out of ten Americans floss daily and 20% of American never floss.[15] The NHANES revealed groups who were more likely to report never flossing including: males over females, age group 75 and older than 30-44 years of age, non-Hispanic blacks and Hispanics over non-Hispanic whites, and low-income patients over higher income brackets.[16,17] Due to low compliance in flossing, clinicians should offer other alternatives that are just as effective.[18]

Oral Health Literacy (OHL)

OHL is defined as the access to and knowledge about good oral behaviors and consequences of poor oral health, access to professional dental care and the ability to understand how to take medications and professional recommendations.[19,20] Health literacy does not reflect intelligence or education of a patient, but can be associated with prognosis, compliance and mortality. Many times, oral health professionals are unaware of poor health literacy in a patient.[21] Lower OHL is related to poorer oral health like periodontal disease and cavities.[19,20,22,23]

A patient with a higher health literacy can communicate more efficiently with their oral care provider. This may lead to fewer complications accessing care, understanding the importance of preventive actions, and sharing critical information with their providers.[24] These patients tend to report better oral health because of an increase in compliance of dental recommendations.[24] To increase compliance one must first enhance patient understanding.[25]

Holtzman et al. recommended that dental providers measure their patients' understanding of dental terms and periodontal disease knowledge before providing patient education.[26]

Motivational Theory

The Transtheoretical Model was developed by Prochaska et al.[27] consisting of stages/processes of change, decisional balance, and self-efficacy as an approach to change behavior.[28] It has been applied to smoking cessation and cancer treatment regimes, and has now been suggested to be used in dental hygiene.[28] In 2003, a model was developed and tested to aid patients step by step in the behavioral change of oral self-care,[29] however, there are no current published studies in the literature with this model design.

Flossing compliance has been shown improvement after motivational messages discussing the benefits of flossing and dangers of not flossing.[30] If a patient is more oriented to avoidance or approach, they will respond better to either hearing the benefits of something or the potential dangers of not doing something.[30] Increasing perceived control and intrinsic motivation with persuasive messages showed significant effect on flossing behavior[31] Motivational interviewing is patient-centered and used to inspire changes in behavioral health. Kopp's systematic review showed that use of this particular interviewing in addition to periodontal therapy could positively influence clinical and psychological factors in the context of oral hygiene.[32]

The purpose of this study was to use patient perspective to investigate patient compliance with interdental devices and assess motivators for the use of an at-home interdental cleaner. It was used to identify barriers, motivation level and OHL of patients regarding interdental plaque control.

STUDY POPULATION AND METHODOLOGY

This mixed methods study was reviewed by the UNC Office of Human Research Ethics and was exempt from further review (IRB #17-1118). This study was part of a larger study titled "Effect of Curved Design Soft-Picks® on Plaque Accumulation on Patients with Signs of Gingivitis." (IRB #16-828). Participants of this study were divided into two groups: Oral B® Glide® Floss (F) and Gum® Soft-Picks (SP).

Quantitative

Quantitative data was collected from a daily diary (Figure 1) and two questionnaires (Figure 2) completed by the participants who completed the larger study. Inclusion criteria for this study included: participants aged 18 -70 years, who were routine manual toothbrush users with little to no experience with interproximal deplaquing devices, such as floss or interdental brush. They had signs and symptoms of gingivitis (defined by: all probing depths (PD) ≤4mm and bleeding on probing (BOP) ≥10% but ≤50% of sites), and may not have any tooth site with ≥5mm PD or ≥3mm clinical attachment loss. They may not have participated in an oral care study in the previous 90 days.

Participants were provided an at-home user experience diary, as well as his/her compliance diary. Participants were instructed on proper completion by the designated research staff. The diary should indicate the level of motivation to use the product and end satisfaction for each encounter. The daily diary (Figure 1) included six questions that were rated on a Likert

scale. Choices varied depending on the topic that was asked of them (e.g., tired, confidence level, etc.).

All participants were provided both questionnaires 1 and 2 (Figure 2) and instructed on proper completion by the designated research staff. Questionnaire 1 asked "how important it is to a patient when choosing a product for between teeth cleaning", and the answers were rated on a Likert scale of 1-5 from not at all important to extremely important. Questionnaire 2 asked "how much the participants agreed that each of the following characteristics accurately describes the product you used during this study." The questionnaires should indicate the level of product familiarity, overall usage satisfaction, as well as motivation to use the product in the future. The scale ranged from disagree strongly to agree strongly.

Data Analysis

The demographics for the 49 participants were analyzed with Proc freq (SAS v. 9.3) and Proc Npar1way to run Chi-square and Wilcoxon Rank Sum Tests. The daily diary and questionnaire responses were analyzed using Exact Mantel-Haenszel Chi-square tests with modified ridit scores comparing the distribution of agreement between groups. P-value was set to $\alpha < .05$.

Qualitative

Inclusion criteria for the qualitative data collection included participants that completed the larger study. All 49 participants were contacted via email and phone with the opportunity to participate in the focus groups.

Two focus group sessions were conducted the summer of 2017. Participants reported to the University of North Carolina School of Dentistry (SOD). They were provided a consent form for voluntary participation, and directed to two private classrooms, based on the interdental

device they used in the larger study. All F participants were in one focus group and the SP participants were in another. Focus groups were facilitated by qualitative research specialists from CHAI Core (NIH funded company specializing in qualitative research). A focus group guide (Figure 3) was developed by research team, and later revised by a research qualitative specialist from CHAI Core. The focus group guide (Figure 3) consisted of 16 questions based on themes of participant periodontal knowledge, periodontal literacy, current behavior, and their feelings about interdental deplaquing. Participants received a monetary incentive and a parking voucher. Sessions were digitally recorded, and files were transcribed by an independent company, Landmark, Associates, Inc. (Figure 4).

Data Analysis

The demographics for the focus groups were analyzed using Fisher's Exact and Wilcoxon Rank Sum tests. Research team members from CHAI Core developed a codebook (Figure 5) based on the focus group guide. The transcribed files were uploaded into ATLAS.ti 7.5.15 program for a thematic qualitative analysis to summarize the participants' oral health habits, knowledge about the importance of interdental deplaquing and available methods, and the barriers and facilitators to interdental deplaquing using the codebook developed by CHAI Core (Figure 5).

RESULTS

Quantitative

Questionnaires 1 and 2

Forty-nine participants completed the Effect of Curved Design Soft-Picks® on Plaque Accumulation on Patients with Signs of Gingivitis at the SOD. The participants were divided into two groups. The SP group had 25 people with the age range of 19-43, and the F group had 24 people with the age range 19-59. There was no statistically significant proportional difference in the groups concerning sex, age, race or ethnicity for the questionnaires and daily diaries (Table 1).

Questionnaire 1 was used to identify patient barriers to interdental deplaquing. There was no statistically significant difference between the F and SP group regarding the importance of 16 characteristics when choosing an interdental deplaquing device. Questionnaire 2 was used to assess the participants' opinion regarding the same 16 characteristics about the interdental deplaquing device they used. Participants in the F group reported a higher percentage of agreement in features involving the effectiveness of the product. There was a statistically significant proportional agreement regarding: 1) removing food and debris from between the teeth ($p=0.02$); 2) provides a thorough clean between the teeth ($p=0.02$); 3) fits easily between the teeth ($p=0.001$); and 4) makes my mouth feel clean ($p=0.01$) (Table 2). In the SP group, participants had a higher percentage of agreement when reporting feelings of ease and convenience with their product. There was a statistically significant proportional agreement

when asked if the product: 1) makes cleaning between the teeth quick (p=0.006); 2) easy (p=0.01); 3) convenient (p=0.003); and 4) easy to hold (0.001) (Table 2). The F group had a statistically significant proportional agreement with the characteristic of the product being difficult to use (p=0.04) (Table 2).

Daily Diary

Data collected from the daily diary was analyzed regarding days of use with a product. For the number of days the interdental product was used, there was a median of 90.0% of days used for the F group and 93.3% of days used in the SP group. There was no statistically significant proportional difference in the number of days a product was used during the 28-day study period between the two groups (p=.66). When asked how tired participants were on the days they were to use the product, 42.6% of the F group (n=47) and 64.3% of the SP group participants (n=47) reported being tired or very tired. When asked how motivated they were to brush their teeth on the days they were to use the product, 50.0% of the F group (n=47) and 51.0% of the SP group (n=47). The level of motivation to clean between their teeth with F at 40.7% (n=46) and SP at 53.6% (n=46). After using the interdental deplaquing method, participants reported 91.1% of days in agreement with the statement the product was easy to use for the SP (n=46) and 79.9% for the F (n=46), and they were greater than 70% confident with how the product was used for both groups (n=47). Sixty-seven percent or higher of days participants of both groups reported being satisfied with the product they used (n=47) with no statistically significant difference between the two groups (Table 3).

Qualitative

Nineteen participants completed the focus groups. The F focus group included 11 participants and the SP group had 8 participants. There was no statistically significant differences regarding age, sex, race or ethnicity between the two focus groups (Table 4).

Floss Experience and Challenges

Participants reported many benefits to being in the study, such as, establishing a maintainable routine and learning how to use the string floss correctly. Challenges reported included: uncertainty about correct flossing technique, belief it could cause aesthetic or health problems, and inconvenience and discomfort. This is represented in the following quotes:

> "I think flossing is just, like, really annoying and inconvenient."

> "When I was flossing, I wasn't sure if I was flossing right even though I know I was taught. And so, like, I felt like if I wasn't doing it right, then what was the point?"

Soft-pick® Experience and Challenges

Participants reported challenges, such as pain and irritation during use, difficulty cleaning between teeth effectively, the end was either too thick, or the length was too short to reach back teeth, some disliked the taste or that it was single use only. Examples of comments to demonstrate this include:

> "If they were a little bit longer and flexible maybe they wouldn't have done that [broken]."

> "The actual pick could not go through, penetrate between the teeth. Not comfortably. "

Facilitators for Improvement

Participants in both groups reported ways to improve the product or compliance with the products. They recommended creating a habit by incorporating it into your daily routine. Other comments suggested modifying the products for easier use. Participants also reported that clinicians should be discussing the initial discomfort for interdental cleaning. Statements to support this include:

> "Create a flossing habit by making it part of daily routine."
>
> "Keep interdental aid in your home where it is easily seen."
>
> "Improve the product or create a service that makes the product easier to use."
>
> "Clinicians should discuss how long patients should expect initial discomfort associated with flossing."

Motivation

Many participants reported only cleaning between their teeth periodically when they felt food trapped between them. Other motivating factors included: wanting their mouth to taste and feel clean, concern about bad breath, and their awareness of the health benefits with good oral hygiene. Reasons for reported lack of motivation included: short-term benefits did not equate to amount of effort required to complete, it was a hassle and time consuming, and they were unclear about the health benefits or felt that it was more of a concern for later in life. Participant comments included:

<u>Motivators</u>

> “I’d say my primary objective above all else is just to have my mouth feel clean and my breath be not too smelly.”

> “I don't feel like my teeth are clean unless I floss them…And I don’t feel like the toothbrush does enough.”

Lack of Motivation

> ”You don't see the benefits [of interdental cleaning] right away.”

> “For me would be it's not that I don't want to or can’t do or don’t like it. It's that I need to be convinced…I'm not sold on it.”

Oral Health Literacy

Knowledge of Interdental Cleaning Importance

When participants were asked what they knew regarding the importance of cleaning in between their teeth, they reported receiving mixed messages about why it is essential and required frequency. Some participants reported awareness of a link between poor oral health and heart disease, and that bacteria could accumulate between your teeth causing gum disease. They also reported hearing that maintaining good oral health could prevent bad breath, salivary stones, TMJ, sleep apnea, gum recession and loss of bone density in teeth and jaws. Most participants were aware that cleaning between their teeth on a regular basis was recommended, but some participants reported that they heard it was unnecessary. Participant comments included:

> “My dentist said she didn't floss every day.

> “There's, like, research out now that you don't have to floss every day.”

Definition of Gum Disease

When asked what came to mind when gum disease was mentioned, participants defined gum disease as bleeding or black gums, inflammation and pockets with rotten teeth and pain. Participants reported being somewhat familiar with these terms they noted but could not define

them, and many quotes showed their lack of knowledge on gum disease. Participant comments included:

> "I haven't heard them use periodontal disease or gum disease for years. …The last thing I remember is there was early 2000's, but they didn't explain what gingivitis was. ….It was just a word that was bad that most people didn't seem concerned about."

> "I know a little bit about the cause, but I have no idea what it looks like or symptoms or what it looks like when you're about to start getting it."

Dental Influencers/ Information Sources

Participants reported that they received their oral health information in many ways, but the most influential time period was during childhood. They described the information they received, and how they learned from their parents and oral health lessons in school or pediatric care. As adults, participants received or actively sought out information from dental providers, internet, and the UNC dental school. They explained that each of these had influenced their oral health decisions. They described ways that the media, through advertisement and product placement, drew their attention to available products and made some appear more appealing than others. This is illustrated by the following comments:

> "Yeah, I remember when I was in school…they would teach you how to brush your teeth, but nobody ever taught us how to floss… "

> "You see 100 ads for toothpaste and toothbrushes a day….I don't think I've ever seen a floss ad ever."

Priorities for Daily Oral Care Practices

To address how these influencers have affected decisions, the focus group facilitator asked about participant priorities in their oral health care at home. They reported brushing one to two times a day at minimum, and sometimes, after each meal. Some daily routine aspects were fixed, like morning brushing, while others changed depending on the activities of the day.

Participants stated:

> "Some toothbrushes actually can get between teeth and do a better job of taking care of that."
>
> "I like mouthwash better to clean between my teeth. I'll use that twice a day, but I might not floss, only once a week or something, whenever I think to pick it up."

DISCUSSION

While studies regarding interdental deplaquing have generally collected quantitative data, few have focused on a qualitative design. There is a need for research to collect data that includes identification of barriers, perceptions of participants, current patient OHL and effect on motivation to interdental plaque control. This mixed methods study provides insight from the participants to allow a better understanding of what prevents a patient from complying/adhering to use of interdental cleaners and what would motivate a patient to be compliant with an at-home interdental cleaner.

Participants revealed in the daily diaries and questionnaires that there was pain or discomfort during flossing, similar to findings by Aguirre et. al[33]. Participants in the Aguirre study knew it was important to floss, but did not comply because of discomfort and bleeding that occurred during flossing.[33] During the focus group, participants in the current study revealed some common themes such as inconvenience, discomfort and irritation with flossing. One participant felt that clinicians should discuss the expected initial discomfort of flossing. Participants found the value of continual flossing for 30 days and how the discomfort wanes once the gingivitis is healed. Clinicians should provide instructions and discuss the possibility of initial discomfort.

Results from this study align with other studies that reveal poor OHL in adults. Wehmeyer et al. investigated the impact of OHL on periodontal health status and found that low OHL in participants related to the severity of periodontal disease in periodontal patients.[20] A lack

of OHL was revealed among current participants during the focus groups. Although some were correct in their one word definitions of gum disease, many could not elaborate what the word meant regarding oral health. Many had heard mixed messages about interdental cleaning, ranging from “my dentist told me they do not floss” to “there’s research out there that says we don’t have to floss.” They felt that gum disease was something “not to be too concerned about” since people do not talk about it much. When discussing influence, they reported that childhood was their most significant influential time but that even during school, brushing was always emphasized, and they were not shown how to floss. Participants reported seeing multiple advertisements for toothbrushes and toothpaste; however, they did not recall the same frequency for floss. Without adequate advertisements and community education, knowledge about interdental plaque devices and importance will not reach the part of the population without access to dental care. Social media, as well, as commercial advertising would be an excellent way to reach this population. Community outreach programs need to be developed to focus on prevention and oral hygiene instructions. School programs could be implemented to assist in reaching the younger population for lifelong behavior development.

Alwaeli et al. revealed low OHL in pregnant women. Most of the women knew the main cause of gum disease, but did not believe they needed to alter their habits to improve their oral health and were unaware of their current oral health state.[34] The study suggested a need for health professionals to discuss the increased risk for periodontal diseases during pregnancy.[34] Female participants in the current study were either at child bearing age or reported having young children. Most reported that their habits developed as a result of how they were raised and what their parents taught them. Bridges et al.[35] and Brega et al.[36] both found an association with low OHL in caregivers and poor oral health status in their children. Parents can be influential in

the development of good oral care. Implementing the knowledge about infant through teenage oral health care into first time parenting classes and programs, or providing pamphlets to first time mothers in physician offices are some steps in the right direction to getting the knowledge out there.

Participants in this study reported a lower motivation for interdental deplaquing in their daily diaries. This result is in line with statistics that show only 4 out of 10 Americans floss daily and 32 percent have never flossed.[15–17] Buunk-Werkhoven et al. showed that two-thirds of the population in his study brushed two times daily, but only a fourth flossed daily.[37] When asked about motivation, participants reported that their motivation to brush was that they wanted a fresh mouth without poor breath. They did not understand the benefits and felt that flossing was a time consuming task. Participants were unaware that people who brush can still have bad breath due to the bacteria left interproximal. Therefore, with lack of OHL their biggest concern, bad breath, may still unveil in their mouth. This is why it is important to increase OHL in patients. Health professionals should be educating their patients, and there needs to be community-based education with educational messages to reach those who are not seeking routine dental care.[38]

In order to begin the process of increasing OHL, oral health care providers should provide more detailed oral hygiene information to their patients. DH can enhance their patients' role in their home care by performing brief health literacy screenings, adjusting oral hygiene instructions to individual patients by using nontechnical language, and encouraging patient questions.[21] DH should raise awareness in the community to reach those who may not be able to afford dental care. These patients are the most concerning since their oral issues may not be addressed quickly. One aspect of OHL is having knowledge of the consequences of poor oral

health and lack of care.[19] Mann et al. showed that patients who were made aware of benefits and risks of not flossing increased their interdental deplaquing compliance.[30] Kamalikhah et al. agreed that perceived benefits was a factor for oral behavior.[39] The participants reported in the focus group that they did not understand the benefits of interdental deplqauing. Patients with higher OHL can communicate more efficiently and typically report better oral health,[24] so the increase in literacy for the public is important. Increasing a parent's OHL should result in better oral health for children[22,23] and teach them habits early to carry through life instead of trying to correct a poor habit during adulthood. This may also increase dental production in offices, since patients with higher OHL tend to keep their dental appointments.[26]

Participants in this study discussed social influences as a determining factor for their oral hygiene care, including friends, family, media and their dental provider. This is supported by Buunk-Werkhoven et al. who showed that motivation of patients was affected by social outcomes.[37] Focus group participants discussed seeing only advertisements for expensive products instead of basic oral care needs and the desire to try some just because of the endorsement on television. This agreed with participants of Aguirre-Zero et al. who reported lack of media messages regarding lifestyle changes to affect oral health.[33] Some of this study's participants reported beginning to use power brushes simply because their family was using it, or their dentist suggested it with great enthusiasm.

Increase in OHL may increase compliance when guidance is provided with a successful behavioral change model. Perceived behavior control, defined as a person's perception of their capability to perform a behavior, was the best predictor of oral hygiene behavior.[37] Another term for this is self-efficacy. Kamalikhah et al. agreed that flossing behavior was influenced by self-efficacy.[39] This was evident in participants who reported dislike of the floss due to its difficulty

of use and difficulty to understand how to use. One participant expressed this, “When I was flossing, I wasn’t sure if I was flossing right even though I know I was taught. And so, like, I felt like if I wasn’t doing it right, then what was the point?” Increasing literacy of how to floss properly, as well as, alternatives will be able to help patients find the most effective and efficient interdental deplaquing device to meet their individual needs. This can be accomplished by methods like the transtheoretical model that focuses on self-efficacy with processes of change.[28] This method has been successful in tobacco cessation and cancer programs and is believed it could work if applied to dental situations.[29] Increasing perceived behavior control through motivational messaging has been shown to increase compliance.[31] Motivational interviewing is a patient centered tool that is effective for behavior changes in oral health.[32] Creating a habit of daily flossing by changing behaviors was an interest for participants of this study.

Finding an overall satisfaction with the ease of use in the SP was expected in the fast-paced society of today. Many individuals seek out products that are quick and easy to use. Despite a statistically significant higher report of tiredness in the SP group, they still reported a higher level of motivation for interdental deplaquing. This may be contributed to the easy use of the product. It was not expected to reveal an overall satisfaction with the cleanliness associated with floss. Despite, the research showing that other interdental deplaquing methods are just as effective,[1,6,7,9,11–13,18,40–46] if not more, in removing plaque; patients may not perceive it that way during use. Why this perception was revealed in our participants is unknown, but one thought is that it may be due to the psychological influence since childhood that floss is the best way to clean between the teeth. Professionals should keep current in the research and offer these other alternatives with the supported information, so that patients are aware, and do not feel limited to the traditional string floss.

Strengths

Strengths of this study include the mixed-methods design. With a mixed methods study not only were we able to receive a quantitative Likert scale answer, we were then able to receive insight into why that answer was chosen during the qualitative focus group. Participants had a unique perspective since they had equal access and consistent experience with the interdental device they discussed. Throughout the study, an unbiased company, Chai Core, who specializes in qualitative research and analysis, guided the committee.

Limitations

Limitations of this study include: a small convenience sample size of participants that were either employed or enrolled in UNC Chapel Hill. There was a better distribution in age range of 19-59 for the quantitative portion, but in the qualitative portion, the SP group only represented ages 21-28. There was no crossover with the interdental devices used. The SP group had no experience with the F and vice versa. This would have given a great perspective to compare the use of both within the same subjects and their perceptions.

Implications for Future Research

Future studies should include a larger sample size to provide a more diverse study population. Another demographic to be added would be socioeconomic status, during childhood and adulthood, in order to compare and contrast influences with status and culture. It would also be beneficial to delve further into literacy by asking patients what they know about interdental deplaquing effectiveness and the options available to them.

CLINICAL RELEVANCE

Scientific Rationale for Study

Qualitative research is needed to identify patient barriers, perceptions, OHL and motivation regarding interdental deplaquing.

Principal Findings

Participants had an overall perceived satisfaction with the effectiveness of the F and ease of use with the SP. Participants showed lack of literacy and motivation regarding interdental deplaquing.

Practical Implications

Oral health providers are responsible for patient education on the causes/effects of poor oral health; and evolving communication skills with motivational interviewing and other behavior models of change can be beneficial. Self-efficacy and time efficiency may increase compliance with an individualized interdental deplaquing device. Providers should be more active in community awareness and advocating public education.

CONCLUSION

This study aimed to assess patients' OHL, motivation level, and barriers regarding interdental deplaquing. Participants had an overall perceived satisfaction with the effectiveness of the F and ease of use with the SP. An overall lack of literacy and motivation regarding interdental deplaquing was found among participants.

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APPENDICES

Figure 1. Daily Diary for Participants

Figure 2. Questionnaire 1 and 2

How important it is to a patient when choosing a product for between teeth cleaning?	Not At All Important	Not Very Important	Somewhat Important	Very Important	Extremely Important
	1	2	3	4	5
Removes food and debris from between teeth					
Provides a thorough clean between teeth					
Fits easily between my teeth					
Is easy to clean back teeth					
Makes between teeth cleaning quick					
Makes between teeth cleaning easy					
Makes between teeth cleaning convenient					
Is easy to hold during use					
Feels comfortable during use					
Makes my mouth feel fresh					
Is easy to understand how to use correctly					
Makes my mouth feel clean					
Are easy to use out of the home					
Is pleasant to use					
Cleans easily around crowns and bridges					

How much the participants agree that each of the following characteristics accurately describes the product you used during this study?	Disagree Strongly	Disagree Somewhat	Agree nor Disagree	Agree Somewhat	Agree Strongly
	1	2	3	4	5
Removes food and debris from between teeth					
Provides a thorough clean between teeth					
Fits easily between my teeth					
Is easy to clean back teeth					
Makes between teeth cleaning quick					
Makes between teeth cleaning easy					
Makes between teeth cleaning convenient					
Is easy to hold during use					
Is difficult to use					
Feels comfortable during use					
Makes my mouth feel fresh					
Is easy to understand how to use correctly					
Makes my mouth feel clean					
Are easy to use out of the home					
Is pleasant to use					
Cleans easily around crowns and bridges					

Figure 3. Focus Group Guide

INTRODUCTION AND ICE BREAKER [5 minutes]	II. Establishing a context for discussing the use of the Soft Pick [10 minutes]	III. Perceptions and attitudes on periodontal disease [15 minutes]	IV. Reactions to participation in research study [25 minutes]
•To help us get to know each other, please tell us your first name only and one thing you like to do in your free time and the current color of your toothbrush. •Group: Soft Pick/ Floss	•Today we will be talking about how people take care of their teeth at home. We will be asking questions in regards to information sources, home habits, and opinions on taking care of your teeth at home. •What do you consider important/ or a priority when it comes to taking care of your teeth at home? •How or where do you go to find out about information on how to take care of your teeth at home? •What influences your decisions around your dental/oral care? Examples: Social media, news, dentist, friends?	•When I say periodontal or gum disease, what comes to your mind? •What have you heard about the importance of cleaning in between the teeth? •Can you tell me how or why some people think that cleaning between the teeth is important? •What might help motivate people to clean between their teeth regularly? •Studies have shown that at this time not everyone uses something to clean between their teeth regularly. If you are someone who is not using something regularly to clean between your teeth, what would make you want to use a product?	•How did participation in this study affect your dental/oral home care habits, if at all? • If there has been a change in your at home dental/oral care, realistically, how long do you think you will continue this change? •What did you think of using the Soft-pick/Floss? •What challenges, if any, did you experience using the Soft-pick/Floss? •What would make it easier for you to use the Soft-pick/Floss? •If you have used floss in the past, how would you compare using the Soft-pick to flossing (only asked in this group)? •Were you able to recognize any change in your gums when using the Soft-pick/Floss regularly? If so, what did you identify as a change?
V. Closing Question [5 minutes]			
•Based on our discussion today, what do you feel are the two main things I should take back to our team? •Is there anything else you feel we did not cover that I need to know?			

FIGURE 4. Summary of Study Organization

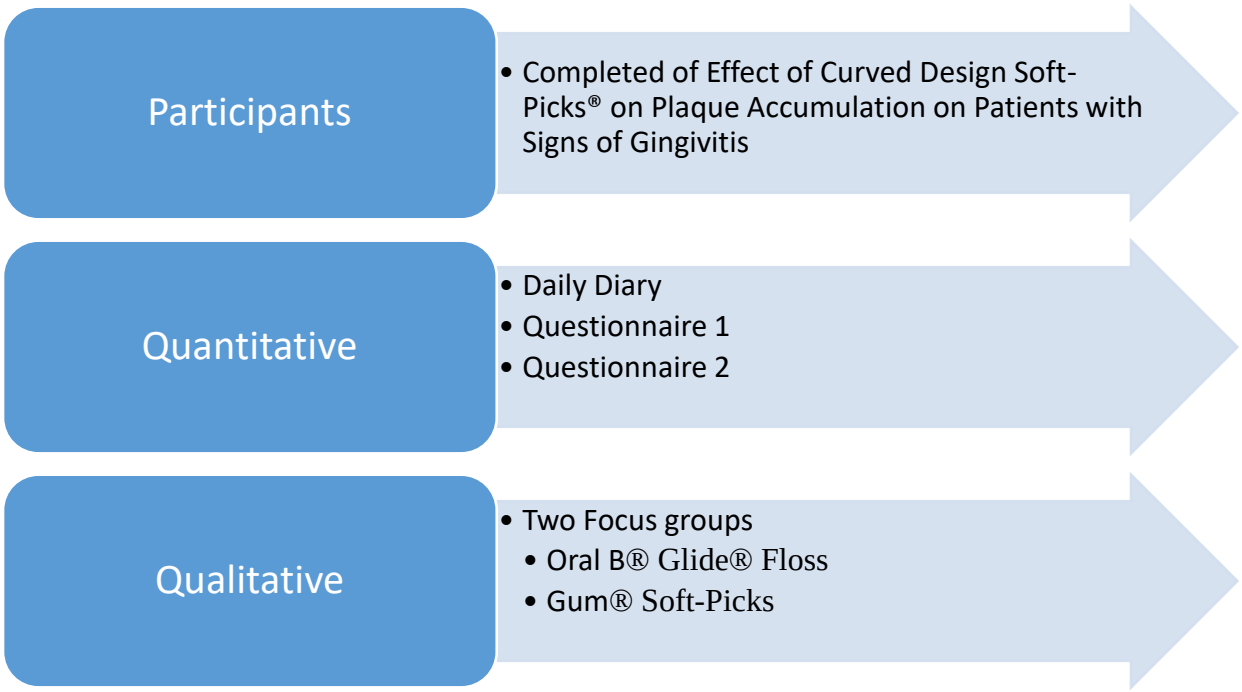

Figure 5. Code Book Themes

- Teeth at home
- Gum disease definition
- Cleaning importance
- Information sources
- Dental influencers
- Cleaning motivators
- Study participation impact control
- Floss challenges
- Floss use facilitators
- Study participation impact intervention
- Soft-pick® challenges
- Soft-pick® facilitators

Table 1. Quantitative Demographics	Soft-pick® (n=25)	Floss (n=24)
Group N=49		
Age Range (years) (p= .88)	19-43	19-59
Race (p=.62)		
Caucasian	20	16
African American	0	2
Other	5	6
Sex (p=.89)		
Female	12	12
Male	13	12
Ethnicity (p=.94)		
Hispanic	5	5
Non-Hispanic	20	19

Table 2. Questionnaire 2 Percentage of Agreement	SP	F	P-Value
Removes food and debris from between teeth	84.0	**95.8**	**.02**
Provides a thorough clean between teeth	52.0	**87.5**	**.02**
Fits easily between my teeth	24.0	**87.5**	**<.0001**
Is easy to clean back teeth	56.0	39.1	.57
Makes between teeth cleaning quick	**80.0**	43.5	**.006**
Makes between teeth cleaning easy	**76.0**	47.8	**.01**
Makes between teeth cleaning convenient	**72.0**	37.5	**.003**
Is easy to hold during use	**92.0**	29.2	**<.001**
Is difficult to use	8.0	**29.2**	**.04**
Feels comfortable during use	44.0	37.5	.45
Makes my mouth feel fresh	36.0	54.2	.25
Is easy to understand how to use correctly	96.0	95.8	1.00
Makes my mouth feel clean	52.0	**79.2**	**.01**
Are easy to use out of the home	**96.0**	50.0	**.009**
Is pleasant to use	64.0	37.5	.10
Cleans easily around my crowns and bridges	33.3	30.4	.98

Table 3. Daily Diary	Answer	% of Days		P-Value
Before Cleaning:		**SP**	**F**	
How tired are you? (N=47)	Tired/Very Tired	64.3	42.6	**.002**
What is your motivation level:				
To clean your teeth? (N=47)	Motivated/ Very Motivated	51.0	50.0	.59
To clean between your teeth? (N=46)		53.6	40.7	.37
After Cleaning:				
Was the assigned product easy to use? (N=46)	Easy/Very Easy	91.1	79.9	.27
How confident are you tonight with the assigned product? (N=47)	Confident/ Very Confident	71.4	76.8	.79
How satisfied are you tonight with how the product cleaned your teeth? (N=47)	Satisfied/ Very Satisfied	67.9	72.3	.69

Table 4. Qualitative Demographics	Soft-pick® (n=8)	Floss (n= 11)
Group (n=19)		
Age Range (years) (p=.24)	21-28	20-59
Sex (p=.65)		
Female (total)	3	6
Male(total)	5	5
Race (p=.60)		
Caucasian(total)	7	7
African American(total)	0	2
Other (total)	1	2
Ethnicity (p=1.00)		
Hispanic	2	3
Nonhispanic	6	8